

[ORAL ARGUMENT NOT SCHEDULED]**No. 24-5290**

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

ARDELYX, INC., ET AL.,**Plaintiffs-Appellants,****v.****ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN
SERVICES, ET AL.,****Defendants-Appellees.**

**On Appeal from the United States District Court
for the District of Columbia**

FINAL BRIEF FOR APPELLEES

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Plaintiffs-Appellants are Ardelyx, Inc.; American Association of Kidney Patients, and National Minority Quality Forum. Defendants-Appellees are Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services; the U.S. Department of Health and Human Services; Dr. Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare & Medicaid Services; and the Centers for Medicare & Medicaid Services.

B. Rulings Under Review

The rulings under review are (1) the Order, Dkt. No. 21 (Nov. 8, 2024) (Joint Appendix (JA) 154), and the Memorandum Opinion, Dkt. No. 22 (Nov. 8, 2024) (JA 155-87), and (2) the Order, Dkt. No. 28 (Dec. 20, 2024) (JA 211), and the Memorandum Opinion, Dkt. No. 29 (Dec. 20, 2024) (JA 212-38), in *Ardelyx, Inc. v. Becerra*, No. 1:24-cv-02095-BAH (D.D.C. filed July 17, 2024) (Beryl A. Howell, J.). The district court's

first opinion is available at *Ardelyx, Inc. v. Becerra*, No. 24-cv-02095 (BAH), 2024 WL 4723068 (D.D.C. Nov. 8, 2024).

C. Related Cases

This case has not previously been before this Court. Counsel for Defendants-Appellees are unaware of any other related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

/s/ Caroline D. Lopez
Caroline D. Lopez

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GLOSSARY

CMS	Centers for Medicare & Medicaid Services
ESRD	End-stage renal disease
FDA	Food and Drug Administration
JA	Joint Appendix
MTD	Motion to Dismiss
Secretary	Secretary of Health and Human Services

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. § 1331. Pls. Br. 5. Concluding that the preclusion provision found at 42 U.S.C. § 1395rr(b)(14)(G) foreclosed plaintiffs' claims, the district court granted the Secretary of Health and Human Service's (Secretary) motion to dismiss and denied summary judgment to plaintiffs on November 8, 2024. *See* Mem. Op., Dkt. No. 22 (Motion to Dismiss (MTD) Op.) (Joint Appendix (JA) 155-87). On December 20, 2024, the district court denied plaintiffs' motion to alter the judgment, or in the alternative, for an injunction pending appeal. Order, Dkt. No. 28 (JA 211); Mem. Op., Dkt. No. 29 (Reconsideration Op.) (JA 212-38). Plaintiffs filed a timely notice of appeal on December 23, 2024. Notice of Appeal, Dkt. No. 30 (JA 239-40). This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

The Medicare program provides health-insurance coverage to qualified individuals who suffer from end-stage renal disease. To encourage the efficient delivery of dialysis services to these patients,

Congress established a bundled payment system that pays end-stage renal disease facilities for all “renal dialysis services.” 42 U.S.C.

§ 1395rr(b)(14)(A)(i). Congress specified that “‘renal dialysis services’ includes” four broad categories of items and services, *id.*

§ 1395rr(b)(14)(B), but otherwise empowered the Secretary to establish and implement the bundled payment system. *See id.* § 1395rr(b)(14)(A).

Congress simultaneously provided that “[t]here shall be no . . . judicial review” of, among other things, the “identification of renal dialysis services included in the bundled payment.” *Id.* § 1395rr(b)(14)(G).

Plaintiffs are advocacy groups and a company, Ardelyx, which manufactures an “oral-only” drug used to treat patients with end-stage renal disease. Plaintiffs argue that their drug should not have been included in the bundled payment.

The question presented is whether subparagraph 1395rr(b)(14)(G) precludes plaintiffs’ challenges to the identification of XPHOZAH (and other oral-only drugs) as renal dialysis services included in the bundled payment.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

Medicare is a federal health insurance program for the elderly and disabled, *see* 42 U.S.C. § 1395 *et seq.*, and the Secretary administers the Medicare program through the Centers for Medicare & Medicaid Services (CMS). Medicare has long provided coverage for people suffering from end-stage renal disease, who need either dialysis or kidney transplantation. *See id.* § 426-1. As relevant for individuals with end-stage renal disease, Medicare Part B covers physician and other outpatient health care services, and Medicare Part D covers prescription medications for beneficiaries who choose to enroll in Part D plans which are administered by private insurance companies.

1. 2008 Medicare Improvement Act Provisions

a. In the 1980s, Congress established a prospective payment system, including for dialysis services. *See* Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, tit. XXI, subtitle B, sec. 2145(a)(7), § 1881(b), 95 Stat. 357, 800 (1981); *see* 42 U.S.C.

§ 1395rr(b)(7). Under a prospective payment system, payment is determined before the service is provided, based on a formula that can include a patient's diagnosis, geographic factors, and other considerations. Prospective payment systems “encourage the more efficient delivery” of services, 42 U.S.C. § 1395rr(b)(7), as facilities can retain any amount of the Medicare payment that exceeds their costs. As relevant here, CMS accordingly established a “composite rate[]” that each facility would receive for each dialysis treatment offered. *See* 48 Fed. Reg. 21,254, 21,255 (May 11, 1983).

At first, this composite rate was comprehensive, covering most routinely provided drugs, laboratory tests, and supplies for the treatment of end-stage renal disease. *See* 75 Fed. Reg. 49,030, 49,032 (Aug. 12, 2010) (codified at 42 C.F.R. § 413.171). Over time, however, facilities began to rely on items and services that were still paid for separately and thus not included in their composite rate payments. *See id.* These separately billable services eventually grew to comprise about 40% of total spending for outpatient maintenance dialysis. *Id.*

b. To address this trend by removing the incentive for dialysis facilities to rely more heavily on drugs reimbursed separately from the

old composite rate, Congress created a new bundled payment system as part of the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, tit. I, subtitle C, pt. II, 122 Stat. 2494, 2553-56 (Medicare Improvements Act). Specifically, Congress directed CMS to “implement a payment system under which a single payment is made . . . to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment.” 42 U.S.C. § 1395rr(b)(14)(A)(i).

In the referenced “subparagraph (B),” Congress elaborated on the term “renal dialysis services.” 42 U.S.C. § 1395rr(b)(14)(A), (B).

Congress specified that the term “includes—”

- (i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;
- (ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;
- (iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and
- (iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

Id. § 1395rr(b)(14)(B). Congress also expressly excluded one item from this definition: the term “renal dialysis services’ . . . does not include vaccines.” *Id.*

Congress also provided for various adjustments to the bundled rate. For example, Congress directed CMS to update the payment amounts annually to “reflect[] changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.” 42 U.S.C. § 1395rr(b)(14)(F)(i)(I). Congress also instructed CMS to provide for various adjustments to the base bundled payment rate for facilities in certain circumstances. *Id.* § 1395rr(b)(14)(D). Such adjustments account for “high cost outliers due to unusual variations in the type or amount of medically necessary care” or for “low-volume facilities.” *Id.* § 1395rr(b)(14)(D)(ii)-(iii).

At the same time, Congress limited the availability of review of CMS’s determinations in implementing this new system. Congress made clear that “[t]here shall be no administrative or judicial review” of, among other things, “the identification of renal dialysis services included in the bundled payment.” 42 U.S.C. § 1395rr(b)(14)(G).

Congress also precluded review of various other aspects of this system

elsewhere in subparagraph 1395rr(b)(14)(G) and in other review bars throughout the statute. *See, e.g., id.* § 1395rr(b)(12)(H), (14)(G), (h)(5).

c. Congress also sought to ensure continued access to quality care, by providing for quality incentives based on a variety of performance standards that would go into effect after January 1, 2012, and would be updated annually. *See* Medicare Improvements Act, sec. 153(c), § 1881(h), 122 Stat. at 2556-59 (codified as amended at 42 U.S.C. § 1395rr(h)). Congress instructed that those performance standards should be established for quality measures that include, “to the extent feasible,” measures that assessed known medical issues associated with end-stage renal disease like “bone mineral metabolism,” as well as general measures like “patient satisfaction.” *See id.* sec. 153(c), § 1881(h)(2)(A), 122 Stat. at 2557 (codified as amended at 42 U.S.C. § 1395rr(h)(2)(A)(ii), (iv)). If dialysis facilities did not perform satisfactorily on these measures in a given year, Congress provided that “payments otherwise made to such provider or facility under the system under subsection (b)(14) for such services shall be reduced by up to 2.0 percent, as determined appropriate by the Secretary.” *Id.* sec. 153(c),

§ 1881(h)(1)(A), 122 Stat. at 2556 (codified at 42 U.S.C.

§ 1395rr(h)(1)(A)).

2. 2010 Implementing Regulation

In 2009, CMS published a notice of proposed rulemaking indicating that it was planning to include “oral-only drugs,” in addition to intravenous drugs and their oral equivalents, as part of the bundled payment pursuant to its authority under the definition of “renal dialysis services.” 74 Fed. Reg. 49,922, 49,928-29 (Sept. 29, 2009). CMS explained that clause (iii) of subparagraph 1395rr(b)(14)(B) directed the agency “to include all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat ESRD, regardless of the route of administration.”¹ *Id.* at 49,928.

In 2010, CMS published the final rule implementing the bundled payment. *See* 75 Fed. Reg. at 49,040. CMS explained that the text “viewed as a whole . . . suggests a comprehensive definition that wraps in all items and services related to outpatient renal dialysis that are furnished to individuals for the treatment of” end-stage renal disease.

¹ Although the government generally uses the full term “end-stage renal disease” in this brief, the government has used the shorter form of “ESRD” when quoting from other sources, including plaintiffs’ brief.

Id. CMS accordingly clarified that, in addition to intravenous or injectable drugs and their oral forms, “renal dialysis services” includes “oral-only ESRD-related drugs (that is, drugs for which there is no injectable equivalent or other form of administration),” *id.* at 49,038, pursuant to its authority under subparagraph (B), *see id.* at 49,038-40.

Having established this general framework, CMS also analyzed which of the separately billable drugs were sufficiently related to end-stage renal disease to qualify for the bundle. *See* 75 Fed. Reg. at 49,047. CMS categorized “drugs and biologicals on the basis of drug action” and evaluated whether each category “would be expected to be utilized for ESRD-related conditions in a dialysis unit.” *Id.* Based on this analysis, CMS determined that drugs in the “bone and mineral metabolism” category—defined as “[d]rugs used to prevent/treat bone disease secondary to dialysis”—are part of the end-stage renal disease bundle. *Id.* at 49,050. The functional category designation process is reflected in the regulation at 42 C.F.R. § 413.234(b)(1).

CMS also addressed commentators’ concerns about adding oral-only drugs to the bundled payment. For example, CMS explained that it did not believe facilities would “seek to maximize profits by resorting to

cheaper but less effective alternatives” to oral-only drugs to the detriment of patient care because facilities must adhere to the principle that “patient care regimens will always be selected solely based on patient needs as identified in the patient’s plan of care.” 75 Fed. Reg. at 49,040-41. Nor would the bundled rate drive facilities to do so because CMS had “developed the bundle, with the inclusion of all oral drugs, to account for the costs that [dialysis] facilities will incur in furnishing these drugs to patients.” *Id.* at 49,041. CMS also emphasized that it would “monitor utilization of renal dialysis items and services to ensure that quality care is being provided,” including through the development of “quality measures for bone and mineral metabolism.” *Id.* at 49,045, 49,047.

Finally, CMS delayed the effective date of its rule to provide time for the agency to further refine the “pricing mechanism” for oral-only drugs and for facilities to adapt their practices in relation to the provision of oral drugs. *See* 75 Fed. Reg. at 49,043.

3. Subsequent Statutory Amendments to the Bundled Payment System

Congress has revisited the statutory language governing end-stage renal disease bundled payments several times, incorporating

various changes in light of CMS's 2010 regulation, which included eligible oral-only drugs in the bundle. Congress delayed the rule's implementation three times, each time acknowledging CMS's determination that oral-only drugs should be included in the bundle. *See American Taxpayer Relief Act of 2012*, Pub. L. No. 112-240, tit. VI, subtitle C, § 632(b), 126 Stat. 2313, 2354 (2013) (delaying the date on which CMS could “implement the policy under [the regulation] . . . relating to oral-only ESRD-related drugs” until 2016); *Protecting Access to Medicare Act of 2014*, Pub. L. No. 113-93, tit. II, sec. 217(a), § 632(b)(1), 128 Stat. 1040, 1061 (extending the delay until 2024); *Achieving a Better Life Experience Act of 2014*, Pub. L. No. 113-295, div. B, tit. II, sec. 204, § 632(b)(1), 128 Stat. 4010, 4065 (extending the delay until 2025). Oral-only drugs therefore became part of the bundled payment effective January 1, 2025.

In the meantime, Congress also enacted provisions to study the impact of CMS's identification of oral-only drugs as part of the bundle, each time acknowledging that CMS had exercised its regulatory authority “under section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)).” *See Patient Protection and Affordable Care Act*,

Pub. L. No. 111-148, tit. X, subtitle C, § 10336, 124 Stat. 119, 974 (2010); Pub. L. No. 112-240, § 632(d), 126 Stat. at 2354-55. In 2010 Congress directed the Government Accountability Office to study “the impact on Medicare beneficiary access to high-quality dialysis services of including specified oral drugs that are furnished to such beneficiaries for the treatment of end stage renal disease in the bundled prospective payment system . . . pursuant to the [2009] proposed rule.” *See* Pub. L. No. 111-148, § 10336, 124 Stat. at 974. And in 2013, Congress instructed the Government Accountability Office to provide an “updated report” analyzing “how the Secretary of Health and Human Services has addressed points raised in the” prior report “with respect to the Secretary’s preparations to implement payment for oral-only ESRD-related drugs in the bundled prospective payment system under section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)).” Pub. L. No. 112-240, § 632(d), 126 Stat. at 2354-55.

Congress also enacted provisions that provided for other ways of protecting quality of care for patients taking oral-only drugs.

Specifically, Section 217(d) of the Protecting Access to Medicare Act amended 42 U.S.C. § 1395rr(h)(2) to require the inclusion of

“[m]easures specific to the conditions treated with oral-only drugs” to assess the performance of dialysis facilities (with the possibility of a potential reduction in bundled rate). Pub. L. No. 113-93, sec. 217(d), § 1881(h)(2), 128 Stat. at 1062 (codified at 42 U.S.C. § 1395rr(h)(2)(E)) (capitalization altered). As a result, if dialysis facilities’ performance with respect to their patients’ “conditions treated with oral-only drugs” fell short on such a measure (as with the measures previously included in the statute), that issue could factor into a 2% reduction in those facilities’ bundled payment rate. *See* 42 U.S.C. § 1395rr(h)(1)(A), (2)(E)(i).

B. Factual Background

Plaintiff Ardelyx’s drug, known as XPHOZAH, is approved to treat patients with chronic kidney disease on dialysis. Compl., Dkt. No. 1, at 12, ¶ 38 (Compl.) (JA 19). XPHOZAH is an oral-only drug that addresses hyperphosphatemia—*i.e.*, the state of having too much phosphate in the blood. Compl. 9 ¶¶ 24-25 (JA 16). When patients suffer from advanced chronic kidney disease, phosphate is not properly excreted from the blood, its levels increase, and hyperphosphatemia commonly results. MTD Op. 29 (JA 183).

On May 13, 2024, CMS rejected Ardelyx's request to exclude XPHOZAH from the bundled payment for renal dialysis services. CMS determined that the drug is a renal dialysis service "because it is furnished to individuals to treat a condition associated with ESRD and is essential to the delivery of maintenance dialysis." Letter from Jonathan Blum, Principal Deputy Administrator, CMS, to Laura Williams, Chief Medical Officer, Ardelyx, Inc. (May 13, 2024), Dkt. No. 1-1, at 1 (XPHOZAH Letter) (JA 60). Because XPHOZAH is an oral-only drug, CMS explained that it would not be included in the bundled payment until January 1, 2025.

CMS encouraged Ardelyx to apply for the Transitional Drug Add-on Payment Adjustment program. XPHOZAH Letter 1-2 (JA 60-61). Under that program, end-stage renal disease facilities may receive an add-on to their bundled payment whenever they use a qualifying drug for up to two years and then receive an add-on to all ESRD payments for up to three years. *See* 42 C.F.R. § 413.234.

C. Prior Proceedings

1. On July 2, 2024, Ardelyx announced that it would not apply for the add-on payment adjustment. Instead, Ardelyx, along with two

advocacy organizations, brought this lawsuit. The government moved to dismiss for lack of jurisdiction, and plaintiffs moved for a preliminary injunction.

2. On November 8, the district court granted the government's motion to dismiss, holding that the statute's preclusion provision bars judicial review of both CMS's "decision to include XPHOZAH in the bundle" and its "regulatory determination" that certain "oral-only renal dialysis drugs . . . are included in the bundle." MTD Op. 12 (JA 166). The statute's preclusion provision mandates that "[t]here shall be no . . . judicial review" of, among other things, "the identification of renal dialysis services included in the bundled payment." 42 U.S.C. § 1395rr(b)(14)(G). That language, the court explained, is "sufficiently broad to reach both categorical determinations made via regulation and specific determinations of individual items" to include in the bundled payment. MTD Op. 13 (JA 167).

The court believed that it could not confirm whether the preclusion provision applied without first addressing whether the agency acted within its statutory authority in identifying oral-only drugs and XPHOZAH as renal dialysis services. *See* MTD Op. 14-19 (JA

168-173) (relying primarily on *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), and *American Hospital Ass’n v. Azar*, 964 F.3d 1230 (D.C. Cir. 2020)). In engaging in that analysis, the court correctly concluded that “CMS did not violate the bounds of its statutory authority” in making those determinations. MTD Op. 28 (JA 182). The statute’s definition of “renal dialysis services,” the court observed, lists four categories of items and services that must be added to the bundled payment, “all introduced with the term ‘includes.’” MTD Op. 21 (JA 175) (quoting 42 U.S.C. § 1395rr(b)(14)(B)). Congress’s use of the word “includes,” instead of a word like “means,” “indicates that the enumerated categories are not exhaustive and others are not foreclosed.” *Id.* (quotation marks omitted).

The court rejected plaintiffs’ argument that subparagraph (B)(iii) shows that Congress intended to exclude oral drugs without “equivalent” non-oral versions. MTD Op. 22 (JA 176) (quotation marks omitted). That subparagraph adds to the bundle “other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral

equivalent form of such drug or biological.” 42 U.S.C.

§ 1395rr(b)(14)(B)(iii). The court explained that plaintiffs’ analysis “ignores the first clause” of that subparagraph, which moves into the bundle “drugs in all forms”—regardless of route of administration—that existed under a separate “reimbursement system prior to ‘application of this paragraph.’” MTD Op. 23 (JA 177).

The court refuted plaintiffs’ suggestion that this reading renders superfluous the second clause’s reference to “any oral equivalent form of such drug or biological,” 42 U.S.C. § 1395rr(b)(14)(B)(iii). “The first clause of subpart (B)(iii) says nothing . . . about drugs that only come into existence *after* ‘application of this paragraph,’ such that ‘payment was’ never ‘made separately under this subchapter.’” MTD Op. 23 (JA 177). “That is where the second part of (B)(iii) does work”: It “contemplates that ‘renal dialysis services’ also includes new, subsequently-developed oral versions of drugs, which were extant in a different form at the time (B)(iii) was applied and were moved into the bundle.” *Id.*

The court emphasized that the statute’s history and purpose reinforce this expansive reading of the statute’s definition of “renal

dialysis services.” MTD Op. 25 (JA 179). “Congress intended to bring more services under the fold of renal dialysis facilities by expanding the [Medicare Improvements Act] bundle.” MTD Op. 26 (JA 180). The court further observed that “inclusion in the bundle” would “create broader access to oral-only drugs, given that 21% of ESRD patients do not have Medicare Part D”—the voluntary prescription drug coverage through which oral-only drugs currently are reimbursed. *Id.* (citing 89 Fed. Reg. 55,760, 55,761 (July 5, 2024)).

The court also made short work of plaintiffs’ assertions that XPHOZAH is not furnished for the treatment of end-stage renal disease within the meaning of subparagraph (B)(iii). The court explained that XPHOZAH treats “a symptom of and problem caused by kidney failure,” and thus is “part of the treatment for [end-stage renal disease]” that can be included in the bundle. MTD Op. 29 (JA 183). The court buttressed that conclusion by reference to FDA’s labeling of XPHOZAH, the ordinary meaning of “treatment,” the necessary meaning of the use of the identical term in a neighboring provision, and various Congressional statements. *See* MTD Op. 28-32 (JA 182-86).

Having concluded that CMS's determinations were consistent with the statute's definition of "renal dialysis services," the court held that further review of plaintiffs' claims was barred by the preclusion provision. MTD Op. 26, 32-33 (JA 180, 186-87). The court accordingly dismissed the complaint for lack of jurisdiction, denied as moot plaintiffs' preliminary injunction motion, and closed the case. MTD Op. 33 (JA 187).

3. Plaintiffs then moved to alter the judgment or enjoin the policy pending appeal.

The court denied plaintiffs' motion. Reconsideration Op. 2 (JA 213). The court explained that plaintiffs advanced a "fundamentally flawed" reading of the court's prior opinion as the basis for reconsideration. Reconsideration Op. 10 (JA 221). The prior opinion "does not opine whatsoever on what is *excluded* from the bundle." *Id.* Rather than interpreting the statute as "exclusive and exhaustive in defining what CMS may consider to be a 'renal dialysis service,'" the opinion "stat[ed] expressly that [the definitional provision] is *inclusive* and *non-exhaustive*." *Id.* The provision sets out four "general categories of items to be included in the bundle" and "a general category of items

that cannot be in the bundle, *i.e.*, vaccines, leaving up to agency discretion both the specifics of the general categories of items or services covered within the terms of [the] subparts . . . , as well as other items or services not generally described.” Reconsideration Op. 12 (JA 223); *see also* Reconsideration Op. 16-17 (JA 227-28). That discretion, the court reasoned, “is clear from the statute as a whole,” which “specifically instructs the Secretary of [Health and Human Services] to establish and execute the bundled payment system” and broadly precludes review of CMS’s determinations. Reconsideration Op. 17 (JA 228).

The court also denied plaintiffs’ alternative request for an injunction pending appeal.

4. On December 23, 2024, plaintiffs appealed and moved for an injunction pending appeal, which this Court denied.

SUMMARY OF ARGUMENT

After separately billable items grew to encompass an increasingly large portion of Medicare spending related to end-stage renal disease, Congress mandated in 2008 that dialysis facilities receive a single payment for all “renal dialysis services.” 42 U.S.C. § 1395rr(b)(14)(A)(i).

Congress simultaneously provided that “[t]here shall be no . . . judicial review” of the “identification of renal dialysis services included in the bundled payment.” *Id.* § 1395rr(b)(14)(G).

Plaintiffs are advocacy groups and a company, Ardelyx, which manufactures the oral-only drug XPHOZAH used to treat patients with end-stage renal disease. In May 2024, CMS identified XPHOZAH as a renal dialysis service that would be added to the bundle effective January 1, 2025.

The district court correctly concluded that Congress’s bar on review of the “identification of renal dialysis services” forecloses plaintiffs’ challenge. Plaintiffs seek to undo CMS’s “identification of” XPHOZAH as a “renal dialysis service[] included in the bundled payment,” asking that the court declare that XPHOZAH is not a ‘renal dialysis service’ and “is not subject to inclusion in the ESRD . . . bundle and instead is a separately coverable drug under Medicare Part D.” Compl., Prayer for Relief ¶¶ 1.a, 1.c. (JA 56). Plaintiffs also take issue with CMS’s 2010 rule identifying qualifying oral-only drugs as renal dialysis services that should be included in the bundle. Both these

challenges fall squarely within the plain terms of the review bar and are therefore foreclosed.

Plaintiffs' repeated contentions that CMS misidentified XPHOZAH fail to take this suit outside the scope of the review bar. The district court was incorrect to look beyond the terms of the statutory preclusion provision, but the court nonetheless reached the correct conclusion, rejecting plaintiffs' baseless contention that because XPHOZAH is an oral-only drug that has no injectable equivalent, it cannot be a "renal dialysis service[]" subject to a bundled payment.

The statutory definition of "renal dialysis services" in subparagraph (B) makes clear that CMS may identify oral-only drugs as renal dialysis services. And Congress's subsequent actions indicate that it agrees with this interpretation of CMS's existing authority.

Turning first to the original text, subparagraph (B) expressly refers to oral drugs, and there is no reason to treat oral-only drugs any differently. In particular, subparagraph (B)(iii) vests CMS with authority to include in the bundled payment "drugs and biologicals . . . furnished . . . for the treatment of end[-]stage renal disease . . . for which payment was (before the application of this paragraph) made

separately under this subchapter.” 42 U.S.C. § 1395rr(b)(14)(B)(iii).

XPHOZAH satisfies both conditions because it is used to treat end-stage renal disease and was billed separately to Medicare Part D prior to its inclusion in 2025. Underscoring the breadth of CMS’s authority, Congress used the term “includes” to introduce the subcategories in subparagraph (B), indicating that such categories were not intended to be exhaustive.

Congressional actions following CMS’s 2010 regulation, which expressly identified oral-only drugs as eligible for inclusion in the bundle, only confirm that oral-only drugs can be included. By the time that qualifying oral-only drugs—including XPHOZAH—were included in the bundle in 2025, Congress had repeatedly acknowledged that such drugs would eventually be included and had updated the surrounding statutory provisions in ways that reflect this eventual inclusion. There can thus be no question that CMS acted within its statutory authority when identifying XPHOZAH as part of the renal dialysis services bundled payment in May 2024.

Plaintiffs nevertheless insist that CMS could not include XPHOZAH because oral-only drugs are supposedly categorically

different from the enumerated items in subparagraph (B). But that argument is predicated on a misunderstanding of the scope of the categories identified in subparagraph (B) and runs headlong into Congress’s subsequent amendments predicated on the inclusion of oral-only drugs. And plaintiffs’ cursory contention that XPHOZAH is not used to treat end-stage renal disease—even though its FDA-approved use is for the treatment of “hyperphosphatemia in individuals with chronic kidney disease on dialysis”—is equally unavailing.

STANDARD OF REVIEW

This Court reviews the district court’s determination whether a preclusion-of-review provision applies de novo. *See, e.g., Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005); *cf. Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515, 518 (D.C. Cir. 2016).

ARGUMENT

The general presumption in favor of judicial review “may be overcome by . . . specific language that is a reliable indicator of congressional intent to preclude judicial review.” *Ascension Borgess Hosp. v. Becerra*, 61 F.4th 999, 1003 (D.C. Cir. 2023) (cleaned up).

Preclusion-of-review provisions are a familiar feature of the Medicare statute, and this Court and other courts of appeals have applied those provisions in accordance with their plain terms to bar review. *See, e.g., id.* at 1002-03, *Texas All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012); *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005); *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004); *American Soc’y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 452 (7th Cir. 2002); *Painter v. Shalala*, 97 F.3d 1351, 1356 (10th Cir. 1996); *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 385-86 (9th Cir. 1996).

The Medicare Improvements Act expressly provides that “[t]here shall be no administrative or judicial review” of “the identification of renal dialysis services included in the bundled payment.” 42 U.S.C. § 1395rr(b)(14)(G). As the district court correctly concluded, plaintiffs challenge exactly that.

I. Subparagraph 1395rr(b)(14)(G)’s Bars Plaintiffs’ Claims

A. In response to rising Medicare costs for renal dialysis services, Congress created a new bundled payment system to bring more drugs and services into a single payment system to pay dialysis facilities. 42

U.S.C. § 1395rr(b)(14)(A)(i). Congress specified that such “renal dialysis services” “include[]” four broad categories of items and services, *id.*

§ 1395rr(b)(14)(B), while otherwise vesting CMS with authority to establish and implement the bundled payment system. *See id.*

§ 1395rr(b)(14)(A). Congress simultaneously provided that “[t]here shall be no . . . judicial review” of, among other things, the “identification of renal dialysis services included in the bundled payment.” *Id.*

§ 1395rr(b)(14)(G).

Plaintiffs’ suit strikes at the heart of this review bar: they challenge CMS’s “identification of” the oral-only drug XPHOZAH as a “renal dialysis service[] included in the bundled payment.”

Plaintiffs’ pleadings confirm that this suit is barred. According to the complaint, plaintiffs challenge a May 2024 letter in which CMS “identified XPHOZAH to be a renal dialysis service” and stated that XPHOZAH would “be included in the [end-stage renal disease] bundled payment system effective January 1, 2025.” Compl. 15, ¶ 54 (JA 22) (quoting XPHOZAH Letter 1 (JA 60)). That letter, by its plain terms, identifies a drug to be included in the renal dialysis services bundle. And plaintiffs allege that CMS’s identification of XPHOZAH as part of

the bundled payment was “arbitrary, capricious, contrary to law, in excess of statutory authority, and short of statutory right, and must therefore be set aside.” Compl. 14 ¶ 44 (JA 21); *see also* Compl. 33 ¶ 145, 37 ¶ 168, 47 ¶ 202, 48 ¶ 215 (JA 40, 44, 54, 55). They seek declaratory relief stating that “XPHOZAH is not a ‘renal dialysis service’ as defined in [Medicare Improvements Act]” and “is not subject to inclusion in the [end-stage renal disease] bundle and instead is a separately coverable drug under Medicare Part D.” Compl., Prayer for Relief ¶¶ 1.a, 1.c. (JA 56). Their challenge thus comes within the plain terms of the review bar and is therefore foreclosed.

To the extent plaintiffs challenge CMS’s 2010 regulation clarifying that renal dialysis services may include certain types of oral-only drugs, that claim likewise is barred by Section 1395rr(b)(14)(G). The ordinary meaning of “identify” includes “to recognize as belonging to a particular category or kind.” *Identify*, Oxford English Dictionary, https://www.oed.com/dictionary/identify_v?tab=meaning_and_use&tl=true#904034 (last visited Mar. 6, 2025). The provision’s reference to CMS’s “identification” of services for the bundle thus “is sufficiently

broad to reach both categorical determinations made via regulation and specific determination of individual items.” MTD Op. 13 (JA 167).

As the district court recognized, application of the preclusion-of-review provision in this case is also consistent with Congress’s desire that end-stage renal disease payments be made efficiently without protracted administrative and judicial review proceedings. Congress determined to bar review of numerous aspects of CMS’s authority “to make important policy judgments in developing the renal dialysis bundle scheme.” *See* Reconsideration Op. 18 (JA 229). For example, subparagraph 1395rr(b)(14)(G) also precludes review of “the determination of payment amounts,” “the establishment of an appropriate unit of payment,” “adjustments” to the payment, “the application of the phase-in” payment mechanism, and “the establishment of the market basket percentage increase factors.” 42 U.S.C. § 1395rr(b)(14)(G); *see also id.* § 1395rr(b)(12)(H) (precluding review of components of the payment calculations). And paragraph 1395rr(h)(5) precludes review of the performance standards or the specification of measures—including the one related to conditions treated by oral-only drugs—and any resulting reductions to the bundled

payment for dialysis facilities. *Id.* § 1395rr(h)(5); *see also, e.g., id.*

§ 1395rr(g)(3) (precluding review of approval of dialysis facilities). Read together, these preclusion-of-review provisions underscore Congress's intent that the agency have "maximum discretion over certain areas without any judicial or administrative interference." *See* Reconsideration Op. 18 (JA 229).

B. Plaintiffs' attempts to circumvent the plain text of the bar are unavailing. Plaintiffs insist that the bar on review of CMS's "identification of renal dialysis services included in the bundled payment," 42 U.S.C. § 1395rr(b)(14)(G), is limited to CMS's determinations that a "*particular*" drug falls within the bundle. Pls. Br. 28; *see* Pls. Br. 28-30. But in so arguing, plaintiffs fail to grapple with the meanings of "identify" discussed above, *supra* p. 27, and raised in the government's trial court briefing, Reply in Support of Mot. to Dismiss 11-12, Dkt. No. 19 (Oct. 16, 2024) (JA 147-48), which foreclose this argument. Plaintiffs instead argue for the supposedly limited scope of the alternate definition of "identify" as "to 'recognize . . . something and say or prove . . . what that . . . thing is.'" Pls. Br. 29 (alterations in original) (quoting MTD Op. 13 (JA 167)) (discussing the district court's

reliance on the Cambridge Dictionary’s definition of “identify”). But nothing in that definition requires that the “thing” that is identified be a single item, rather than a class or type of item. The provision’s reference to CMS’s “identification” of services for the bundle is “sufficiently broad” to reach both. *See* MTD Op. 13 (JA 167).

In any event, plaintiffs do not complain of the regulation’s acknowledgement that oral-only drugs could be added to renal dialysis services bundle in a vacuum but rather complain that the addition of XPHOZAH to the bundle—consistent with this regulation—was arbitrary and capricious and contravened the statute. Even under the terms of plaintiffs’ own argument, therefore, they challenge an “identification.” At the very least, their challenge is “inextricably intertwined” with their challenge to the identification of their individual drug and therefore comes within the review bar. *See, e.g., Florida Health Scis. Ctr, Inc. v. Secretary of Health & Human Servs.*, 830 F.3d 515, 519 (D.C. Cir. 2016) (quoting *Texas All. For Home Care Servs. v. Sebelius*, 681 F.3d 402, 411 (D.C. Cir. 2012)).

Indeed, plaintiffs could not have alleged any concrete injury based on the regulation standing alone. That is because the regulation leaves

open the question of whether a particular oral-only drug comes within the category of oral-only drugs that can be included in the renal dialysis services bundle. The regulation would have had no practical consequences for plaintiffs if CMS had not subsequently decided in the May 2024 letter that XPHOZAH was one such qualifying oral-only drug. As a result, plaintiffs' only cognizable injury is the inclusion of their particular drug in the bundle, which they have previously acknowledged would be the type of individualized identification that would come within the bar.

II. Plaintiffs Err In Arguing That Their Claims May Proceed Because the Secretary Misidentified Their Drug

A. It Is Not Necessary to Consider Whether the Secretary Properly Identified XPHOZAH

Although the district court looked beyond the plain terms of the review bar to the statutory definition of “renal dialysis services” to determine whether the challenged agency action comes within the scope of the review bar, that was unnecessary, and this Court need not do so.

In urging this approach, plaintiffs rely primarily on *Amgen* and *American Hospital Ass’n v. Azar*, 964 F.3d 1230 (D.C. Cir. 2020). See Pls. Br. 30-35 (discussing *Amgen*, 357 F.3d 103, and *American Hospital*

Ass’n, 964 F.3d 1230); *see also* MTD Op. 16-18 (JA 170-72). But those cases cannot assist plaintiffs. Those cases involved a preclusion provision that expressly cross-referenced other provisions of the Medicare statute. *See* 42 U.S.C. § 1395l(t)(12)(A) (precluding judicial review of “the [prospective payment] classification system under paragraph (2), including . . . other adjustments . . . described in paragraph (2)(F)”). This Court thus held that interpreting that provision’s scope required a determination whether the agency action was consistent with the cross-referenced provisions. *See Amgen*, 357 F.3d at 111-13; *accord American Hosp. Ass’n*, 964 F.3d at 1237-38. So too in *COMSAT Corp. v. FCC*, 114 F.3d 223 (D.C. Cir. 1997), on which plaintiffs also rely, this Court looked to surrounding statutory text where the relevant provision expressly incorporated that text by barring review of “[i]ncreases or decreases in fees made by amendments pursuant to this paragraph,” 47 U.S.C. § 159(b)(3) (1994). *Compare* Pls. Br. 32 (relying on *COMSAT*, 114 F.3d at 227), *with COMSAT*, 114 F.3d at 227 (discussing 47 U.S.C. § 159(b)(3) (1994)).

That reasoning is inapposite here, where Congress used the term “identification of renal dialysis services included in the bundled

[Medicare] payment” with no express cross-reference to other provisions of the statute. The question then is whether the Secretary identified, that is, “recognize[d],” XPHOZAH “as belonging to a particular category or kind.” *Identify*, Oxford English Dictionary, *supra*. The Secretary plainly did so. CMS’s identification of XPHOZAH as a renal dialysis service to be included in the bundled payment therefore comes within the plain terms of subparagraph 1395rr(b)(14)(G).² No additional analysis is required.

B. In Any Event, the Inclusion of Oral-Only Drugs Accords with Subparagraph 1395rr(b)(14)(B)’s Definition of “Renal Dialysis Services”

1. Subparagraph (B) Authorizes CMS to Include Oral-Only Drugs in the Bundled Payment

Assuming the question is properly before the Court, the district court correctly rejected plaintiffs’ contention that because XPHOZAH has no injectable equivalent it is somehow exempt from the commonsense conclusion that it is a “renal dialysis service[]” subject to a bundled payment. MTD Op. 28 (JA 182).

² Because plaintiffs nowhere make an *ultra vires* argument, this Court need not consider whether it would have jurisdiction to entertain such an argument. *But see, e.g., DCH Reg’l Med. Ctr. v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019).

a. After separately billable items grew to encompass an increasingly large portion of Medicare spending, *see supra* p. 4, Congress mandated in 2008 that dialysis facilities receive a “single payment” for all “renal dialysis services,” and directed CMS to “implement” that system. 42 U.S.C. § 1395rr(b)(14)(A)(i). Congress further specified in 42 U.S.C. § 1395rr(b)(14)(B) that “the term ‘renal dialysis services’ includes” four categories of items and services:

(i) those that were included in the original composite rate, *id.* § 1395rr(b)(14)(B)(i);

(ii) a particular type of drug that was separately billed at the time (“erythropoiesis stimulating agents and any oral form of such agents”), *id.* § 1395rr(b)(14)(B)(ii);

(iii) “other” separately billed “drugs and biologicals . . . furnished . . . for the treatment of end[-]stage renal disease . . . for which payment was (before the application of this paragraph) made separately under this subchapter,” as well as “any oral equivalent form” of those drugs, *id.* § 1395rr(b)(14)(B)(iii); and

(iv) a catch-all encompassing “diagnostic laboratory tests and other items and services” not included in the original composite rate that are furnished for treatment of end-stage renal disease, *id.* § 1395rr(b)(14)(B)(iv).

Congress also expressly excluded one item from the definition: “Such term does not include vaccines.” *Id.* § 1395rr(b)(14)(B). As the district court recognized, the language and structure of the statute show that

Congress “set[] the minima or floor for ‘renal dialysis services’” by “requir[ing] the agency to include certain items” listed in subparagraph (B) but also “le[ft] CMS to add more drugs as the agency implements and maintains the bundle over time.” Reconsideration Op. 17 (JA 228).

When first proposing how to interpret that subparagraph shortly after it was enacted, CMS made clear its view that the route of administration (injectable, oral and injectable, or oral-only) is irrelevant to whether a drug is a renal dialysis service. Specifically, CMS explained that it viewed subparagraph (B)(iii) as directing the agency “to include all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat ESRD, regardless of the route of administration.” 74 Fed. Reg. at 49,928.

In finalizing that rule, CMS explained that subparagraph (B)(iii) “viewed as a whole . . . suggests a comprehensive definition that wraps in all items and services related to outpatient renal dialysis that are furnished to individuals for the treatment of” end-stage renal disease. 75 Fed. Reg. at 49,040. CMS accordingly clarified that, in addition to intravenous or injectable drugs and their oral forms, “renal dialysis services” includes “oral-only ESRD-related drugs (that is, drugs for

which there is no injectable equivalent or other form of administration),” *id.* at 49,038, pursuant to its authority under subparagraph (B), *see id.* at 49,038-40.

At the same time, CMS ensured that any drugs brought into the bundle would be sufficiently related to the treatment of end-stage renal disease by categorizing “drugs and biologicals on the basis of drug action” and evaluating whether each category “would be expected to be utilized for ESRD-related conditions in a dialysis unit.” *See* 75 Fed. Reg. at 49,047. The agency concluded that “drugs used to prevent/treat bone disease secondary to dialysis” qualified, *id.* at 49,050, again regardless of whether the drug was an intravenous drug, an oral-equivalent drug, or an oral-only drug. As relevant here, CMS subsequently determined that the oral-only drug XPHOZAH qualified because it was “furnished to individuals to treat” one such “condition associated with ESRD and is essential to the delivery of maintenance dialysis.” XPHOZAH Letter 1 (JA 60).

b. The statutory definition of “renal dialysis services” contains ample textual clues that CMS has authority to include oral-only drugs that treat end-stage renal disease in the bundled payment. As an initial

matter, Congress clearly contemplated that the definition of “renal dialysis services” would apply to drugs that were intended to be taken orally, as two subparts of definitional subparagraph (B) expressly cover “any oral form of such [erythropoiesis stimulating] agents,” 42 U.S.C. § 1395rr(b)(14)(B)(ii), and “any oral equivalent form of such drug or biological,” *id.* § 1395rr(b)(14)(B)(iii). MTD Op. 22 (JA 176).

The same is true for oral-only drugs. As the district court explained, “[s]ubparagraph (B)(iii) most directly incorporates into ‘renal dialysis services’ oral-only drugs by covering ‘drugs and biologicals,’ other than [erythropoiesis stimulating agents], that were previously reimbursed separately from the bundle. MTD Op. 22 (JA 176). That provision vests CMS with discretion to add qualifying oral-only drugs to the bundled payment to the extent that they are “drugs and biologicals . . . furnished . . . for the treatment of end[-]stage renal disease . . . for which payment was (before the application of this paragraph) made separately under this subchapter.” 42 U.S.C. § 1395rr(b)(14)(B)(iii).

XPHOZAH, like certain other oral-only drugs, satisfies both conditions set out in this provision. First, such drugs are “furnished” for the treatment of end-stage renal disease, even if not dispensed by

facilities during dialysis. *See* MTD Op. 30-32 (JA 184-86) (holding that timing or location of patients’ intake of a drug “is of no matter,” given Congress’s use of the “broad phrase ‘furnished . . . for the treatment of end stage renal disease’” and intent to expand the “renal dialysis services” bundle). Second, because XPHOZAH was previously reimbursed under Medicare Part D “before the application of this paragraph” in 2025, *see* Pls. Br. 19, such payment was “made separately under this subchapter,” 42 U.S.C. § 1395rr(b)(14)(B)(iii)—*i.e.*, “[s]ubchapter XVIII, which includes Medicare Parts A, B, C, *and* D,” Reconsideration Op. 22 (JA 233), *see also* 75 Fed. Reg. at 49,039 (explaining that subparagraph (B)(iii) sweeps in “all drugs [that] are reimbursable under Medicare by virtue of being authorized for payment under Title XVIII,” including drugs “covered under Part B and formerly covered under Part D”).³

Although XPHOZAH came into existence before the application of this paragraph and can be included in the bundle under subparagraph

³ By abandoning their prior argument that this statutory reference was restricted to reimbursement under Medicare Part B in the opening brief, plaintiffs appear to have conceded the point and we will not belabor it further here. *See, e.g., Board of Regents of the Univ. of Wash. v. EPA*, 86 F.3d 1214, 1221(D.C. Cir. 1996).

(B)(iii), CMS also properly concluded that the statute allows for the inclusion of oral-only drugs that are developed after the paragraph is first applied. To the extent that those drugs are the “oral equivalent” of a drug that came into the bundle under the first clause of subparagraph (B)(iii), the new drug would be added to the bundle under the second clause of (B)(iii). *See* 42 U.S.C. § 1395rr(b)(14)(B)(iii); MTD Op. 23 (JA 177). And to extent that the drug did not exist at the time the paragraph was first applied, CMS has authority under subparagraph (B)(iv) to include such newly developed items and services.

Specifically, subparagraph (B)(iv) provides for the inclusion of “diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.” 42 U.S.C. § 1395rr(b)(14)(B)(iv). Subparagraph (B)(i), in turn, says that the bundle includes items and services in the composite rate as of the day before the effective date of the End-Stage Renal Disease Prospective Payment System. *Id.* § 1395rr(b)(14)(B)(i). Some diagnostic laboratory services were separately billed before that effective date, so it is unsurprising that Congress would identify them specifically as included in the bundle. *See* CMS, Pub. No. 100-02,

Medicare Benefit Policy Manual ch. 11, § 20.2 (Mar. 1, 2019), <https://perma.cc/E5BK-3FT2>. But it is also unsurprising that Congress might have wanted to ensure “items and services” that did not exist on December 31, 2010—for example, drugs and biologicals developed after that date—were included in the bundle once they became available, as long as they are “furnished to individuals for the treatment of end stage renal disease.” Subparagraph (B)(iv) is thus best understood as ensuring that CMS may include newly developed items and services that are not otherwise covered by the prior clauses in the End-Stage Renal Disease bundle.

Finally, to the extent that there might be concern about whether XPHOZAH and other oral-only drugs fit neatly into the subparagraph (B) clauses, the district court cogently explained why Congress’s use of the term “includes,” to introduce these categories demonstrates that “the enumerated categories are not exhaustive and others are not foreclosed.” MTD Op. 21 (JA 175). Had Congress wanted to create an exhaustive list as plaintiffs contend, *see* Pls. Br. 53, it could have used a more restrictive word, like “means,” *see* MTD Op. 21 (JA 175), *see also*, *e.g.*, *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012)

(observing that use of “the verb ‘includes’ instead of ‘means’ . . . makes clear that the examples enumerated . . . are intended to be illustrative, not exhaustive”). Tellingly, Congress used the word “means” to define three other terms in the same statute, “demonstrating that the more restrictive word would have been used in subparagraph (B) if Congress so intended.” *See* Reconsideration Op. 11 (JA 222);⁴ *cf. United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1114-15 (D.C. Cir. 2009) (per curiam) (explaining that “[b]y switching between ‘means’ and ‘includes’ in the same definitional provision, Congress signaled its intent to distinguish between exhaustive and non-exhaustive lists”).

So too, Congress’s choice to expressly exclude “vaccines” from the term “renal dialysis services,” without placing any similar restriction on oral-only drugs, provides additional textual support for the district court’s (and CMS’s) reading of the scope of CMS’s authority. *See* 42

⁴ *See* 42 U.S.C. § 1395rr(b)(8) (“[T]he term ‘home dialysis supplies and equipment’ *means* medically necessary supplies and equipment . . . required by an individual suffering from end stage renal disease in connection with renal dialysis carried out in his home” (emphasis added)); *id.* § 1395rr(b)(9) (“[T]he term ‘self-care home dialysis support services’, to the extent permitted in regulation, *means*—” (emphasis added)); *id.* § 1395rr(b)(10) (“[T]he term ‘self-care dialysis unit’ *means* a renal dialysis facility or a distinct part of such facility” (emphasis added)).

U.S.C. § 1395rr(b)(14)(B). That language underscores that Congress knew how to expressly exclude items when it wanted to, while “leaving up to” CMS’s “discretion both the specifics of the general categories of items or services covered within the terms of subparts (B)(i)-(iv), as well as other items or services not generally described in subparagraph (B) at all, since the subparts are prefaced by the word ‘includes.’”

Reconsideration Op. 12 (JA 223).

2. Plaintiffs’ Arguments to the Contrary are Flawed

Plaintiffs insist that CMS’s inclusion of oral-only drugs in the 2010 regulation “ignore[s] Congress’s specific directives” and “negate[s] the limitations Congress imposed” in the statute because oral-only drugs are supposedly categorically different from various enumerated items in subparagraph (B). *See* Pls. Br. 53. But that argument parses Congress’s intent too finely. And it cannot be squared with Congress’s subsequent amendments to the statute, which implicitly acknowledge that oral-only drugs can be included in the bundle. Plaintiffs’ textual arguments fare no better. The district court thus correctly rejected plaintiffs’ attempts to carve out an exception for their challenge to CMS’s inclusion of XPHOZAH in the bundle.

a. Exclusion of Oral-Only Drugs Cannot Be Squared With Congressional Intent, as Confirmed by Subsequent Amendments

Nowhere in their opening brief do plaintiffs grapple with the evidence, relied on by the district court, of Congress's intent regarding the inclusion of oral-only drugs in the end-stage renal disease bundled payment. For the reasons explained below, all congressional action in this area leads inexorably to the conclusion that Congress left open the door for CMS to include oral-only drugs in the bundled payment and approved CMS's decision to do so.

1. As even plaintiffs acknowledge, the Medicare Improvements Act changed the payment system “to promote the cost-effective provision of renal dialysis services by dialysis facilities.” Pls. Br. 40. Congress did so by instructing CMS to “bring more services under the fold of renal dialysis facilities by expanding the [Medicare Improvements Act] bundle.” MTD Op. 26 (JA 180). Including oral-only drugs in the bundle serves that goal by controlling Medicare costs for those drugs while still ensuring that they are available to patients.

First, including oral-only drugs in the bundled payment “ensure[s] that patient care is not skewed by financial incentives” to prescribe

items outside the bundle so as to receive higher reimbursement. *See* 75 Fed. Reg. at 49,040; *see also* MTD Op. 26 (JA 180). It also builds on the “operational efficiency” gained from including oral-equivalent drugs that plaintiffs acknowledge are part of the bundle. *Cf.* 75 Fed. Reg. at 49,032. That is particularly true because dialysis facilities already had to make the adjustments to their relationships to pharmacies (or by building out their own dispensing capacities) to “ensure a smoother transition to the dispensing of” those oral-equivalent drugs that, like XPHOZAH, are not provided at the time of dialysis. *See id.* at 49,043.

Finally, inclusion in the bundle can also provide broader access to oral-only drugs that would otherwise only be covered for those who choose to enroll in a plan with Part D coverage and pay associated premiums. As CMS recently explained, “incorporation of oral-only drugs into” the “bundled payment beginning January 1, 2025, . . . will expand access to the 21 percent of the ESRD population who do not have Part D coverage.” *See* 89 Fed. Reg. at 55,761; *see also* MTD Op. 26 (JA 180) (same).

2. Congress has also embraced the inclusion of oral-only drugs in the bundle through its legislative actions. In amending the Medicare

statute, Congress has repeatedly referenced CMS's inclusion of oral-only drugs in the bundled payment as proposed in the 2009 notice of proposed rulemaking and adopted in the 2010 final rule. *See* Pub. L. No. 112-240, § 632(b), 126 Stat. at 2354; *see generally supra* pp. 10-13.

Rather than repudiating CMS's statutory authority to include oral-only drugs under 42 U.S.C. § 1395rr(b)(14), as one would expect if plaintiffs were correct, Congress amended the statutory provisions governing the bundled payment system in ways that make sense only if it agreed with CMS. Specifically, Congress delayed implementation of the regulation's inclusion of oral-only drugs in the bundle three times, twice ordered the Government Accountability Office to submit studies on the impacts of such inclusions on renal dialysis centers and beneficiaries, and ultimately amended the program to provide for a performance measure that could be a basis for reducing the bundled payment if a dialysis facility performed poorly as to conditions treated by oral-only drugs. *See supra* pp. 10-13.

In 2013, for example, Congress directed three actions that implicitly assume the validity of the regulation's inclusion of oral-only drugs. First, Congress delayed the implementation of the regulation

“relating to oral-only ESRD-related drugs in the ESRD prospective payment system” until 2016. Pub. L. No. 112-240, § 632(b)(1), 126 Stat. at 2354. Second, Congress ordered CMS to “monitor the bone and mineral metabolism of individuals with end stage renal disease” as part of its “implementation of oral-only ESRD-related drugs in the ESRD prospective payment system under subsection (b)(14) of section 1881 of the Social Security Act (42 U.S.C. 1395rr(b)(14)).” *See id.* § 632(b)(2), 126 Stat. at 2354. Finally, Congress ordered the Government Accountability Office to prepare and submit a report “analyzing how the Secretary of Health and Human Services has addressed points raised in” a prior Government Accountability Office report “with respect to the Secretary’s preparations to implement payment for oral-only ESRD-related drugs in the bundled prospective payment system under section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)).” *See id.* § 632(d), 126 Stat. at 2354-55.

And the next year, Congress instructed CMS to add a measure “specific to the conditions treated with oral-only drugs” as one of the factors that could lead to a 2% reduction in the bundled payment to dialysis facilities that performed poorly. *See* Pub. L. No. 113-93, sec.

217(d), § 1881(h)(2), 128 Stat. at 1062 (codified at 42 U.S.C.

§ 1395rr(h)(2)(E)) (capitalization altered). These directives would make little sense if CMS lacked statutory authority to include oral-only drugs in the bundled payment rate.

Congress enacted these changes without altering the existing definition of renal dialysis services in subparagraph (B) that CMS had invoked when including oral-only drugs in the bundle in the 2010 rule. “[W]hen,” as here, “Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the ‘congressional failure to revise or repeal the agency’s interpretation is persuasive evidence that the interpretation is the one intended by Congress.’” *See Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 846 (1986) (quoting *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 275 (1974)). That maxim has particular salience here: When Congress revisited the statute in light of the challenged regulation’s inclusion of oral-only drugs as part of the bundled payment, Congress amended the statute to delay (but not forbid) the implementation and to further provide for further reductions to dialysis facilities’ bundled payment

based on their performance on measures specific to the treatment of conditions treated by oral-drugs.

**b. Plaintiffs' Countervailing Arguments
Fall Flat**

1. Plaintiffs first insist that Congress only intended the bundled payment to cover “injectable drugs and biologicals administered intravenously during dialysis—and their oral equivalents” because those were the separately-billed drugs that were profitable at the time. *See* Pls. Br. 40. As the district court emphasized, Congress was not so narrowly focused. *See* MTD Op. 25 (JA 179).

Congress acted against the backdrop of the prior bundled rate’s failure to include enough services, which had led to skewed financial incentives to use more expensive drugs and services outside of the bundle. Congress “intended to bring more services under the fold of renal dialysis facilities by expanding the [renal dialysis services] bundle.” MTD Op. 26 (JA 180). Nor was there any indication that this interest was limited to just those particular outside drugs that were, as plaintiffs describe it “[then-]profitable,” Pls. Br. 40 (alteration in original) (quotation marks omitted). As the district court observed, oral-only drugs also serve as “alternative modes of treatment already in the

bundle” even if they do so through different means. MTD Op. 26 (JA 180).

XPHOZAH “is used as an add-on therapy in patients with chronic kidney disease who are on dialysis who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.” XPHOZAH Letter 1 (JA 60). In other words, it is an alternative or additional mode of treatment to phosphate binders, which are already covered in the bundle. And, contrary to plaintiffs’ assertions, the inclusion of oral-only drugs at this juncture benefits from the operational efficiencies developed in response to the earlier inclusion of oral-equivalent drugs. *See supra* p. 44.

In making this argument, plaintiffs singularly focus on one unenacted bill that would have amended the renal dialysis services provision to expressly reference oral-only drugs. *See* Pls. Br. 42-43 (relying on America’s Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 1232). Plaintiffs argue that Congress’s rejection of this later-proposed bill that would have amended subparagraph (B)(ii) to expressly reference oral-only drugs means that CMS must have erred as

to its construction of the originally enacted (and still extant) language in (B)(ii). *See id.*

As the district court emphasized, however, the decision not to enact particular legislation amending existing provisions sheds no light on what the unamended text means. For example, an “equally permissible inference is that Congress saw the amendment as unnecessary because the statute already broadly authorized CMS to include oral-only drugs in ‘renal dialysis services.’” MTD Op. 27 (JA 181). Courts thus “can infer nothing from the Congress’s consideration and rejection of a differently worded provision in a separate piece of legislation.” MTD Op. 28 (JA 182) (quoting *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1130 (D.C. Cir. 2017) (discussing the same proposed bill)).⁵ That is especially true here, where Congress adopted other bills

⁵ In any event, if this Court considers such unenacted bills, it bears noting that a more recent unenacted bill underscores that Congress recognizes that the inclusion of oral-only drugs like XPHOZAH as of 2025 is the default and that any exceptions to that default would require amendment to the statute. In 2023, Congress considered but did not enact a bill that would have delayed implementation of the regulation with respect to a subset of “oral-only ESRD-related drugs in the ESRD prospective payment system” that is “indicated for the reduction, management, or control of the serum phosphate of an individual, until the earlier of January 1, 2033” or the

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that amended the single payment program in ways that only make sense if oral-only drugs could be included in the bundle under the current wording of subparagraph (B)(iii). *See supra* pp. 10-13.

Plaintiffs’ policy concerns get them no farther. For example, their underutilization concerns (Pls. Br. 40-41), depend on the “assum[ption] that outside-the-bundle oral-only drugs are both more expensive and more effective than those in the bundle.” MTD Op. 26 (JA 180). But that assumption is not true as to every oral-only drug, as both the district court and CMS have emphasized. *See id.*; *see also, e.g.*, 75 Fed. Reg. at 49,040. Moreover, the Transitional Drug Add-on Payment Adjustment, which provides for an add-on payment for certain drugs for up to two years and can lead to additional payment for up to three years, gives dialysis facilities more flexibility to “incorporate new drug and biological products and make appropriate changes in their businesses to adopt such products.” 84 Fed. Reg. 60,648, 60,654 (Nov. 8, 2019); *see also* 42 C.F.R. § 413.234. That allows dialysis facilities to try out these new drugs while receiving an increased level of payment to account for

time that the FDA approved an intravenous drug for that treatment. *See* Kidney PATIENT Act of 2023, H.R. 5074, 118th Cong. § 2.

additional costs of incorporating such new products into their businesses.

And plaintiffs’ objection (Pls. Br. 40-41) that providers might prescribe lower-cost but less-effective oral-only drugs, instead of XPHOZAH, are addressed by provisions governing the bundled payment system. Those provisions hold dialysis facilities responsible for ensuring that “patient care regimens will always be selected solely based on patient needs.” 75 Fed. Reg. at 49,041. As discussed *supra* pp. 12-13, those protections include the use of performance measures—including one that measures “conditions treated with oral-only drugs”—that can result in the reduction of a bundled payment for poor performance. Including oral-only drugs in the bundle, while also imposing such safeguards, thus encourages “physicians” to “evaluate the potential use of less expensive equally effective alternatives for the treatment of conditions associated with ESRD,” and use them “where those alternatives are available and not contraindicated by the patient’s clinical status.” *Cf.* 75 Fed. Reg. at 49,041.⁶

⁶ Congress also provided for other ways to adjust the base rate to compensate dialysis facilities in designated circumstances where

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2. Plaintiffs’ primary textual contention is that the category of included items in subparagraph (B)(iii) necessarily excludes oral-only drugs. They insist that CMS can only include that subset of oral drugs identified in the second half of subparagraph (B)(iii), *i.e.*, those that are the “oral equivalent” of the “drugs and biologicals . . . for which payment was (before the application of this paragraph) made separately under this subchapter” identified in the first half of subparagraph (B)(iii), 42 U.S.C. § 1395rr(b)(14)(B)(iii). *See* Pls. Br. 38-39. According to plaintiffs, this reference to the inclusion of oral drugs “equivalent” to non-oral drugs means that CMS lacked authority to also include oral-only drugs that necessarily have no such equivalent. They opine that Congress would have expressly incorporated oral-only drugs into subparagraph (B)(iii) if they were intended to be included. *See id.*

But, as the district court observed, the “flaw in plaintiffs’ reasoning is that” it “ignores” that the ““drugs and biologicals”” identified in that first half of that subparagraph includes oral-only

patient costs are unusually high, including for outliers, rural facilities, and patients with characteristics that result in higher costs for dialysis facilities. *See* 42 U.S.C. § 1395rr(b)(14)(D); *see also* 42 C.F.R. §§ 413.232, 413.233, 413.235, 413.237.

drugs that were reimbursed separately “before the application of this paragraph” to such drugs. MTD Op. 23 (JA 177) (quoting 42 U.S.C. § 1395rr(b)(14)(B)(iii)); *see also supra* pp. 35-42 (discussing how qualifying oral-only drugs come within this clause). “That clause serves to move drugs in all forms that exist under a fee-for-service reimbursement system prior to ‘application of this paragraph’ into the bundle system.” MTD Op. 23 (JA 177). With respect to the type of oral-only drugs identified in the 2010 regulation, the paragraph was not applied until 2025 by operation of statutory amendments delaying the application of the regulation, with the result that such oral-only drugs are included in the bundle under the first clause of subparagraph (B)(iii).⁷ And the second clause of (B)(iii) then would allow for the

⁷ Because these congressional amendments altered the effective date of the statutory provision with respect to such drugs, the Court need not address the exact metes and bounds of whether the relevant date for the parenthetical was the statute’s original effective date of January 1, 2011, or the later effective date of when the statutory provision would be applied to a particular drugs (or class of drugs) to include them in the bundle. In any event, Congress knew how to use the effective date of the statute when it wanted to, as it did by requiring the inclusion of “items and services included in the composite rate for renal dialysis services as of December 31, 2010” earlier in the same provision. *See* 42 U.S.C. § 1395rr(b)(14)(B)(i). That difference in wording further supports the district court’s interpretation of the use of the different

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addition of “new, subsequently-developed oral versions of [those] drugs” identified in the first clause that did not exist at the time that the bundled system first applied to that category of drugs. *Id.*

Plaintiffs also argue that the district court’s interpretation of subparagraph (B)(iii) excludes other drugs currently in the bundle and hamstring CMS’s authority to include future drugs. *See* Pls. Br. 49-50. In discussing what must be included in the bundle under subparagraph (B)(iii), however, the district court made clear that it had not “opine[d] whatsoever on what is *excluded*.” Reconsideration Op. 10 (JA 221). Instead, the court explained that Congress’s definition of “renal dialysis services” “establish[es] specific rules on what is *required* to be included in the bundle while allowing CMS also to include additional things.” Reconsideration Op. 16 (JA 227). Consistent with that framework, the court held only that “CMS did not violate the bounds of its statutory authority” when it included in the bundle general categories of oral-only drugs as well as a specific drug, XPHOZAH. Reconsideration Op. 15 (JA 226) (quoting MTD Op. 28 (JA 182)). And, as explained above, *supra* pp.

term “before the application of this paragraph” as indicating that the relevant time period for the purpose of that subparagraph might differ from the time that the statute first went into effect.

38-40, to the extent that a new drug or service might be developed that was not strictly required to be included under (B)(iii), it could be included pursuant to CMS's catchall authority under subparagraph (B)(iv).

Moreover, other amendments to the statute refute plaintiffs' concerns (Pls. Br. 49) about CMS's authority to include new drugs by making clear that CMS must "establish a process" for doing so. *See, e.g.*, Pub. L. No. 113-93, § 217(c), 128 Stat. at 1062 (codified at 42 U.S.C. § 1395rr note). As part of the Protecting Access to Medicare Act of 2014, Congress instructed the Secretary to "establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the bundled payment under [the Medicare end-stage renal disease prospective payment system]." *Id.* Notably, Congress did so as part of legislation that simultaneously delayed the date on which CMS could implement its regulation providing for the inclusion of oral-only drugs pursuant to its existing statutory authority under subparagraph (B), which Congress left otherwise unaltered. *See id.* sec. 217(a), 128 Stat. at 1061. This amendment indicates that Congress "recognized that

subparagraph (B) left the inclusion of such items up to CMS,” while “provid[ing] instruction for CMS to exercise that discretion already extant in subparagraph (B) to ensure that such new injectable and intravenous drugs were included in the bundle.” Reconsideration Op. 14 n.3 (JA 225 n.3).

Plaintiffs are also incorrect to suggest that the court’s reliance on the term “includes” as being a reason to read subparagraph (B) as non-exhaustive is inconsistent with CMS’s interpretation of the statute. *Contra* Pls. Br. 54-55. Like the district court, CMS explained that the definition of “renal dialysis services,” when “viewed as a whole, . . . suggests a comprehensive definition that wraps in all items and services related to outpatient renal dialysis that are furnished to individuals for the treatment of ESRD.” 75 Fed. Reg. at 49,040. CMS went on to explain why the inclusion of oral-only drugs was consistent with the third category referring to separately billable “drugs and biologicals.” *See id.* at 49,039-40. CMS’s approach is entirely consistent with the district court’s approach.

2. Plaintiffs’ critique of subparagraph (B)(iv) as a catchall provision also falls flat. As explained above, *supra* pp. 38-40, inclusion

of “diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease,” 42 U.S.C. § 1395rr(b)(14)(B)(iv), is a residual provision that, among other things, vests CMS with discretion to include drugs—including oral-only drugs—that are developed after the bundled payment system is first implemented but serve the same function as services already included in the bundle. Plaintiffs counter that this reading “negates Congress’s choice to enumerate specific categories of drugs” and “would render [subparagraphs] (ii) and (iii) superfluous” because “[a]ny drug, biological, or oral equivalent form that falls within [subparagraphs] (ii) and (iii) necessarily would qualify as ‘items and services not described in [subparagraph] (i) that are furnished to individuals for the treatment of end stage renal disease.’” Pls. Br. 44; *see also* Pls. Br. 46.

But by including drugs that are similar to those that are included under the prior subparagraphs but for their invention date, subparagraph (B)(iv) addresses a different subset of drugs than (B)(ii) and (B)(iii). And because including such drugs under subparagraph (B)(iv) serves the same purpose as those prior subparagraphs, it also

fits comfortably within the canon of ejusdem generis, which posits that “a general or collective term at the end of a list of specific items is typically controlled and defined by reference to the specific classes that precede it.” *Fischer v. United States*, 603 U.S. 480, 487 (2024) (cleaned up). Understood in this manner, it makes all the more sense that this provision would have been written by reference to subparagraph (B)(i), which pulled in those drugs and services that had already been identified as part of the prior composite rate before this new statute went into effect and therefore necessarily existed before this aspect of subparagraph (B)(iv) would be doing any work.

This understanding of subparagraph (B)(iv) is thus entirely different from the statutory interpretations at issue in the cases on which plaintiffs rely. In those cases, courts rejected interpretations of residual phrases when the identified action sought to be swept in through the residual clause was too different in kind from the enumerated agency actions. *Cf.* Pls. Br. 45-46 (first citing *Fischer*, 603 U.S. at 495, and then citing *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 114-15 (2001)).

In *Fischer*, the Supreme Court limited a criminal catchall clause to activities “undertaken with the intent to impair an object’s integrity or availability for use in an official proceeding” like the enumerated actions in the prior clause, explaining that holding otherwise “would override Congress’s careful delineation of which penalties were appropriate for which [enumerated] offenses” in other provisions in the same statute and would be inconsistent with the Court’s general approach to obstruction statutes. 603 U.S. at 489-90, 492-95, 497. In *Circuit City*, the Court limited a reference to “any other class of workers,” 9 U.S.C. § 1, to the types of transportation workers akin to the “seamen” and “railroad employees” previously enumerated. *Circuit City*, 532 U.S. at 114-15. No such concerns adhere here, where the new drugs and services added to the bundle under subparagraph (B)(iv) would be similar in function to the drugs and services included into the bundle under the prior provisions and also would carry out Congress’s instructions to CMS to establish a procedure for doing so.

3. Finally, plaintiffs’ critique that the district court placed too much reliance on the term “includes” depends on the faulty predicate that subparagraph (B)’s categories are narrow. *See* Pls Br. 52-54. As

described above, *supra* pp. 40-41, Congress used three general categories and a fourth catch-all here, which is a textual clue supporting a non-exhaustive list. *See* Reconsideration Op. 11 n.1 (JA 222 n.1); *see also Christopher*, 567 U.S. at 162-63). The cases on which plaintiffs rely are distinguishable because they interpreted the use of the term “includes” in the context of very different statutes. *See* Pls. Br. 53 (first citing *Carcieri v. Salazar*, 555 U.S. 379, 391-92 (2009); and then citing *Dong v. Smithsonian Inst.*, 125 F.3d 877, 880 (D.C. Cir. 1997)).

For example, the Supreme Court’s narrow reading of the residual clause in *Carcieri* turned on the Court’s explanation that the relevant term “Indian” was defined by reference to “discrete definitions” that stood in contrast to Congress’s subsequent choices to expand the agency’s authority with respect to tribes that would not have come within that definition in subsequently enacted provisions. *See Carcieri*, 555 U.S. at 391-92; Reconsideration Op. 11 n.1 (JA 222 n.1). And the Court’s analysis in *Dong* likewise turned on the idea that the plaintiff’s reading of the catchall phrase would sweep in a type of entity that was too unlike the enumerated entities, while also reiterating “the word

‘includes’ normally does not introduce an exhaustive list but merely sets out examples of some ‘general principle.’” 125 F.3d at 879-80.

C. XPHOZAH Is Furnished to Treat End-Stage Renal Disease

Plaintiffs briefly contend that CMS could not have identified XPHOZAH as part of the bundle because it is not “furnished to individuals for the treatment of end stage renal disease” as required to be a renal dialysis service under subparagraph (B)(iii). *See* Pls. Br. 55 (citing 42 U.S.C. § 1395rr(b)(14)(B)(iii)-(iv) and implementing regulations). They assert that XPHOZAH is used to treat the “closely related” condition of “hyperphosphatemia,” which they describe as “correlated” to but not the same as end-stage renal disease itself. *See* Pls. Br. 55-57. But plaintiffs offer no answer to the district court’s cogent rejection of this view based on the scope of FDA’s approval of XPHOZAH, the ordinary meaning of the term “treatment,” and the use of the term in subparagraph (B), and legislative enactments. Indeed, plaintiffs’ treatment in the opening brief is so cursory as to waive any counter they may have, but, in any event, any such arguments would be futile. *Cf. Sierra Club v. FERC*, 867 F.3d 1357, 1378-79 (D.C. Cir. 2017).

Furnishing XPHOZAH in accordance with its only FDA-approved use —*i.e.*, to treat hyperphosphatemia “in adults with chronic kidney disease *on dialysis*”—easily maps onto a common-sense understanding of a renal dialysis service. *See* XPHOZAH Letter 1 (JA 60) (emphasis added) (citing FDA labeling); *see also* MTD Op. 29 (JA 183). Contrary to plaintiffs’ assertions that any such relationship is merely “correlated,” Pls. Br. 55, the district court noted that “[h]yperphosphatemia is most commonly *caused* by advanced chronic kidney disease because phosphate is normally excreted by functioning kidneys.” MTD Op. 29 (JA 183) (Cleveland Clinic, *Hyperphosphatemia*, <https://my.clevelandclinic.org/health/diseases/24293-hyperphosphatemia> (last visited Mar. 3, 2025)); *see also id.* (noting that “80% of ESRD patients on dialysis have hyperphosphatemia”). XPHOZAH treats “a symptom of and problem caused by kidney failure,” and thus is “part of the treatment for ESRD” that can be included in the bundle. *Id.*

This reading accords with the ordinary meaning of treatment. As the district court pointed out, the Cambridge Dictionary’s definition of “treatment” is “the use of drugs, exercises, etc. to *improve the condition* of an ill or injured person, *or to cure a disease*” MTD Op. 30 (JA 184)

(quoting *Treatment*, Cambridge Dictionary, <https://perma.cc/VF7T-AWE5> (emphasis added)). “For chronic diseases like ESRD without a cure,” see Compl. ¶ 5 (JA 10), “a drug that mitigates the symptoms of the disease by replacing a lost function is ‘treatment’ for the disease, even though the drug does not address the underlying cause of the failed organ.” MTD Op. 29 (JA 183). The court analogized XPHOZAH’s use in “reducing toxins in the bloodstream to replace the function of the kidneys” to a similar—“albeit impractical”—function of dialysis, which even plaintiffs readily acknowledge is a treatment. *See id.*

The district court also demonstrated that plaintiffs’ proposed definition of the term “furnished to individuals for the treatment of end stage renal disease” in subparagraph (B)(iii) is incompatible with the necessary meaning of the use of that identical term in subparagraph (B)(ii). *See* MTD Op. 31 (JA 185). Subparagraph (B)(ii) provides for the inclusion of erythropoiesis stimulating agents that are “furnished to individuals for the treatment of end stage renal disease.” But those agents are furnished to treat anemia, rather than end-stage renal disease. The term “treatment of end stage renal disease,” must therefore include treatment of at least some conditions associated with

end-stage renal disease in subparagraph (B)(iii). *See id.* Plaintiffs' opening brief fails to engage with this analysis, much less identify which types of treatments do count in their view and how they can be distinguished from the XPHOZAH's use.

Rather than rebutting these points, plaintiffs posit that including XPHOZAH is inconsistent with CMS's analysis of other drugs. *See* Pls. Br. 55-57. Not only is that type of arbitrary and capricious claim clearly precluded by the review bar, *see, e.g., Knapp*, 875 F.3d at 1128, but it is also incorrect. CMS explained in its 2010 rulemaking how it developed the end-stage renal disease functional categories, and why drugs in the "bone and mineral metabolism" functional category are renal dialysis services, while drugs that treat "diabetes, cardiac conditions, and hypertension" are not. *See* 75 Fed. Reg. at 49,047; *see also id.* at 49,050. That plaintiffs do not like CMS's explanation does not mean that the agency failed to provide a reasoned one.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,640 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Century Schoolbook 14-point font, a proportionally spaced typeface.

/s/ *Caroline D. Lopez*
Caroline D. Lopez

CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2025, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system.

/s/ Caroline D. Lopez
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ADDENDUM

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42 U.S.C. § 1395rr(b)

§ 1395rr(b). Payments with respect to services; dialysis; regulations; physicians' services; target reimbursement rates; home dialysis supplies and equipment; self-care home dialysis support services; self-care dialysis units; hepatitis B vaccine

(14)(A)(i) Subject to subparagraph (E), for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this subchapter to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment (including a payment adjustment under paragraph (12)(B)(ii)) and for such services and items furnished pursuant to paragraph (4).

(B) For purposes of this paragraph, the term “renal dialysis services” includes--

(i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and

(iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

Such term does not include vaccines.

(G) There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of the

determination of payment amounts under subparagraph (A), the establishment of an appropriate unit of payment under subparagraph (C), the identification of renal dialysis services included in the bundled payment, the adjustments under subparagraph (D), the application of the phase-in under subparagraph (E), and the establishment of the market basket percentage increase factors under subparagraph (F).

42 U.S.C. § 1395rr(h)**§ 1395rr(h). Quality incentives in the end-stage renal disease program****(1) Quality incentives****(A) In general**

With respect to renal dialysis services (as defined in subsection (b)(14)(B)) furnished on or after January 1, 2012, in the case of a provider of services or a renal dialysis facility that does not meet the requirement described in subparagraph (B) with respect to the year, payments otherwise made to such provider or facility under the system under subsection (b)(14) for such services shall be reduced by up to 2.0 percent, as determined appropriate by the Secretary.

(B) Requirement

The requirement described in this subparagraph is that the provider or facility meets (or exceeds) the total performance score under paragraph (3) with respect to performance standards established by the Secretary with respect to measures specified in paragraph (2).

(C) No effect in subsequent years

The reduction under subparagraph (A) shall apply only with respect to the year involved, and the Secretary shall not take into account such reduction in computing the single payment amount under the system under paragraph (14) in a subsequent year.

(2) Measures**(A) In general**

The measures specified under this paragraph with respect to the year involved shall include--

- (i)** measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy;
- (ii)** to the extent feasible, such measure (or measures) of patient satisfaction as the Secretary shall specify;
- (iii)** for 2016 and subsequent years, measures described in subparagraph (E)(i); and
- (iv)** such other measures as the Secretary specifies, including, to the extent feasible, measures on--
 - (I)** iron management;
 - (II)** bone mineral metabolism; and
 - (III)** vascular access, including for maximizing the placement of arterial venous fistula.

(E) Measures specific to the conditions treated with oral-only drugs**(i) In general**

The measures described in this subparagraph are measures specified by the Secretary that are specific to the conditions treated with oral-only drugs. To the extent feasible, such measures shall be outcomes-based measures.

(ii) Consultation

In specifying the measures under clause (i), the Secretary shall consult with interested stakeholders.

(iii) Use of endorsed measures**(I) In general**

Subject to subclause (I), any measures specified under clause (i) must have been endorsed by the entity with a contract under section 1395aaa(a) of this title.

(II) Exception

If the entity with a contract under section 1395aaa(a) of this title has not endorsed a measure for a specified area or topic related to measures described in clause (i) that the Secretary determines appropriate, the Secretary may specify a measure that is endorsed or adopted by a consensus organization recognized by the Secretary that has expertise in clinical guidelines for kidney disease.

42 U.S.C. § 1395rr (Note)**NOTE. DRUG DESIGNATIONS**

Pub. L. 113–93, title II, §217(c), Apr. 1, 2014, 128 Stat. 1062 , provided that: As part of the promulgation of annual rule for the Medicare end stage renal disease prospective payment system under section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)) for calendar year 2016, the Secretary of Health and Human Services (in this subsection referred to as the 'Secretary') shall establish a process for-

- (1) determining when a product is no longer an oral-only drug; and
- (2) including new injectable and intravenous products into the bundled payment under such system.

42 U.S.C. § 1395rr (Note)**NOTE. DELAY OF IMPLEMENTATION OF ORAL-ONLY ESRD-RELATED DRUGS IN THE ESRD PROSPECTIVE PAYMENT SYSTEM; MONITORING**

Pub. L. 112–240, title VI, §632(b), Jan. 2, 2013, 126 Stat. 2354 , as amended by Pub. L. 113–93, title II, §217(a), Apr. 1, 2014, 128 Stat. 1061 ; Pub. L. 113–295, div. B, title II, §204, Dec. 19, 2014, 128 Stat. 4065 , provided that:

(1) Delay.-The Secretary of Health and Human Services may not implement the policy under section 413.174(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD-related drugs in the ESRD prospective payment system), prior to January 1, 2025. Notwithstanding section 1881(b)(14)(A)(ii) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(A)(ii)), implementation of the policy described in the previous sentence shall be based on data from the most recent year available

(2) Monitoring.-With respect to the implementation of oral-only ESRD-related drugs in the ESRD prospective payment system under subsection (b)(14) of section 1881 of the Social Security Act (42 U.S.C. 1395rr(b)(14)), the Secretary of Health and Human Services shall

monitor the bone and mineral metabolism of individuals with end stage renal disease.